

Part 2-Pending Claims with Markings and Indications to Show Changes

9. (~~Original~~Amended Once) An introducing member (19) for the ~~insertion of a device~~ inserting the urine draining apparatus defined in claim 13 into the bladder in accordance with one or more of the above claims, wherein

~~an extended cavity runs through the entire,~~ wherein:

~~the introducing member (19), the cavity's dimensions correspond to the external dimensions of the tube-shaped body (10), so that the tube-shaped body (10) can be received therein when in an extended position.~~

has a length sufficient to extend from the exterior opening of the urinary canal through the urinary canal;

the introducing member has a transverse dimension to fit within the urinary canal from the exterior opening of the urinary canal to the bladder neck;
and

the introducing member defines a cavity extending entirely along the length of the introducing member, the cavity having transverse dimension to receive the body of the urine draining apparatus therein when the body is temporally straightened.

10. (~~Original~~Amended Once) An introducing member (19) for the ~~insertion~~ inserting the urine draining apparatus defined in claim 13 into the bladder of a tube-shaped body (10) in accordance with one or more of the above standing claims, ~~wherein,~~ wherein:

~~the introducing member (19) is comprised of~~ is elongated has a length sufficient to extend from the exterior opening of the urinary canal through the urinary canal;

the introducing member comprises a flexible guide thread having an external dimension that is less than that of the tube-shaped body's (10) inner dimension, so that the introducing member (19) can be received within the tube-shaped body (10) to fit within the inner space of the body; and

the flexible guide ~~thread is comprised with~~has sufficient rigidity so that the tube-shaped body (10) assumes an extended position when the introducing member (19) is inserted therein. to temporarily straighten the body upon positioning the flexible guide within the inner space of the body and to insert the body and the flexible guide while within the inner space from the exterior opening of the urinary canal through the urinary canal and to introduce the urine draining apparatus into the bladder.

Part 3--Remarks

This Amendment and Response is responsive to the office action mailed June 5, 2002. In the June 5 office action, claims 1-8 were rejected under 35 U.S.C. 112 as indefinite; claims 1-6 and 8 were rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,176,664 to Weisman; and claim 7 was rejected under 35 U.S.C. 103(a) as obvious from Weisman, in view of U.S. Patent No. 6,368,340 to Malecki et al. In addition, confirmation of a previous telephone election to a restriction requirement was also requested.

Reconsideration of these rejections and the restriction requirement is respectfully requested with respect to the new and amended claims 9, 10 and 13-35 which are now pending.

Restriction Requirement

It is confirmed that a provisional election of claims 1-8 was made by telephone and the election was made without traverse. It is noted that if a generic claim of the elected species is found allowable, the applicant is entitled to consideration of species claims 9 and 10.

The elected claims 1-8 pertain to an apparatus for draining urine from the bladder. Although elected claims 1-8 have been canceled, the subject matter of those claims has been continued in new claims 13-35, which are directed to an apparatus for draining urine from the bladder. Therefore, the new claims 13-35 are consistent with the restriction requirement and the election.

Claims 9 and 10 have been amended to place them in better form and in condition for allowance, because it is believed that new generic claim 13 should be allowable. This action is again consistent with the restriction requirement.

New Claims

New independent claim 13 and new dependent claims 14-35 incorporate and continue the subject matter of the original claims 1-8 in the manner set forth.

The new claims do not present new matter. The specification provides a basis for the subject matter set forth in the new claims in the following locations, among others:

bladder: original claim 1
bladder neck: page 4, line 5
urethra: original claim 1
obstruction: page 1, line 9 and page 3, line 13
urinary canal: page 3, line 23
exterior opening of the urinary canal: original claim 1
human being: original claim 1
elongated body: page 3, line 15 and page 6, line 3
curved, coiled or spiral shape: page 3, line 15 and Fig. 1
spring-like characteristic: page 4, line 11 and page 6 line 9
external force: page 3, line 18
inner space: original claim 6
first end: original claim 1
second end: original claim 5
opening: page 3, line 15 and page 6, line 4
exterior of the body: page 3, line 15 and page 6, line 4
first end piece: original claim 5 and page 6, line 4
second end piece: original claim 7
curved exterior end configuration: page 6, line 6 and Fig. 1
pliable characteristic: page 6, lines 4-5
thread: original claim 1
sufficient length: page 6, lines 12-16
pulling force: original claim 1
location exterior to the exterior opening of the urinary canal: page 6, line 16

flow path for urine: page 7, lines 1,2
marker: page 4, line 7
predetermined location: page 4, lines 8-9
stop: page 3, line 22 and page 6, line 17
handle: page 3, line 22
position which remains outside of the exterior opening of the urinary canal: page 6, line 16
elasticity: original claim 7 and page 6, line 11
through opening: original claim 6
plurality of openings: original claim 8 and page 3, line 20
plurality of spaced apart locations: page 7, line 2
tube: original claim 1 and page 3, line 15
flexible material: original claim 4
generally curved shaped portion: original claim 5 and Fig. 1
curved or rounded end configuration: original claim 5 and page 6, line 6, Figs. 1, 7, 8
at least one opening: Fig. 1
transverse dimension: page 8, lines 16-17 and the Drawings
introducing member: original claim 9
cavity: original claim 8
flexible guide: page 7, line 6 and original claim 10
external dimension: original claim 10
sufficient rigidity: page 10, line 13 and original claim 10
straightened configuration: page 6, line 9 and page 7, line 15
relatively greater elasticity: page 6, line 11
generally spherically shaped portion: page 6, line 6
maximum transverse dimension: original claim 9, 10 and Fig. 1 and 2

generally circular transverse cross-sectional configuration: page 6,
line 6 maximum cross-sectional diameter: original claim 9, 10 and
Figs. 1 and 2

maximum diameter of the body: original claim 9, 10 and Figs. 1 and 2

Indefiniteness Rejection

The new claims 13-35 and the amendments to claims 9 and 10 are intended to resolve all of the indefiniteness issues noted in original claims 1-8.

Anticipation Rejection

Reconsideration of the previous anticipation rejection based on Weisman is requested as it might now apply to new claims 13-35 and amended claims 9 and 10.

New claim 13 incorporates subject matter from original claims 1, 5 and 7. Original claim 7 was rejected as obvious and not anticipated, thereby indicating that the original anticipation rejection based on Weisman was inapplicable to claim 7. Because new claim 13 incorporates subject matter from claim 7, the previous anticipation rejection should not now be applicable to new claim 13.

In addition, new claim 13 recites, in the manner set forth, first and second end pieces which extend across the inner space of the body. The Weisman reference discloses a catheter having open ends. No end pieces extend across the open ends of Weisman's catheter.

Accordingly, the pending claims are believed not to be anticipated by Weisman.

Obviousness Rejection

Reconsideration of the obviousness rejection based on Weisman and Makecki is respectfully requested, as that original obviousness rejection might apply to new and amended claims 13-35, 9 and 10.

As noted above, Weisman does not describe or suggest the use of first and second end pieces connected across the ends of a body. The end pieces, as

recited more specifically in independent claim 13, are intended to facilitate movement of the urine drainage apparatus. The first end piece facilitates movement of the straightened body in the urinary canal and urethra and into the bladder. The curved exterior end configuration of the first end piece is useful in guiding the temporarily straightened body through the urinary canal. The second end piece facilitates the repeated insertion and removal of the other end of the normally curved body into and out of the bladder neck and the urethra, when the thread is pulled. The second end piece also facilitates straightening the other end of the normally curved body so that it can move from the bladder through the bladder neck and into the urethra when the urine is to be drained from the bladder.

The second end piece and the second end of the normally curved body will be inserted through the bladder neck and into the urethra in this manner many times during use. Because of the repeated use in this manner to drain the urine, the second end piece has pliability characteristics to facilitate this movement and to minimize aggravation to the bladder neck as the second end piece is pulled into the bladder neck and urethra and as the second end of the body is temporarily straightened in its movement into the urethra.

Thus, the first and second end pieces, which extend across both open ends of the body, serve the purposes of facilitating movement of the urine draining apparatus into the bladder in the first instance and during repeated long-term use, movement into and out of the bladder neck and the urethra each time that urine is drained.

Weisman fails to recognize either of these improvements or to suggest a basis for such improvements. Instead, Weisman does not use any end pieces on his open catheter. Weisman's open ends would not appear to facilitate such movement, and particularly would not appear to achieve the improvements and benefits of avoiding irritation to the bladder neck from repeated insertion and removal of the second end piece and second end of the body. The first and

second end pieces recited in claim 13 create irritation to the bladder neck and avoid or limit possible pain or discomfort to the user. The features, benefits and improvements of the first and second end pieces, which are not disclosed or suggested by Weisman, are believed to present nonobvious patentable subject matter in new claim 13.

Malecki is not relevant or related to urine drainage apparatus. While Malecki does show a cannula, it is apparently used within blood vessels for endovascular delivery from a forward tip end of the device. Even if the forward tip end of the Malecki device is soft, the other or rear end of Malecki's cannula would appear to remain outside of the body. Nothing in Malecki relates to the concept of continually moving the rear end of the cannula in and out of an opening such as the bladder neck on a repeated, continual use basis under circumstances where it is desirable to avoid undue irritation to tissue surrounding that opening and any resulting pain or discomfort to the user. Indeed, nothing in Malecki remotely relates to repeatedly moving both ends of a catheter into and out of a body canal.

Neither Weisman nor Malecki incorporates the end pieces on an elongated body to facilitate movement of that elongated body in both directions in a body canal. Weisman does not suggest a reason for incorporating subject matter from Malecki. Malecki is not related in nature, operation or use to urine drainage and suggests no reason for it to be combined with Weisman. Only the present application teaches the concept of two end pieces at opposite ends of an elongated body to facilitate movement of the body in both directions in the urinary canal to obtain effective urine drainage, as pertains to claim 13. Accordingly, it is believed that claim 13 is not obvious from Weisman and Malecki.

Dependent claims 14 and 15 relate, in the manner set forth, to a marker attached to the thread. The purpose of the marker is to indicate the extent to which to pull the thread for movement of the second end piece and the second end

of the body past the obstruction to the urethra. Such features are not disclosed or suggested by Weisman or Malecki.

As noted above, the rear end of the Malecki device remains outside of the body, and therefore there is no issue of indicating how far to pull a device located entirely within the body in order to pass an interior obstruction which is not visible on the exterior of the body. Weisman also avoids this issue by describing that the opening end of the catheter is apparently pulled completely out of the urethra and beyond the sphincter (see Fig. 2 and column 2, lines 62-67). Since Weisman requires the end of his catheter to be pulled completely out of the urinary canal for urine drainage, rather than only past the obstruction in the urethra, there is no reason for Weisman to mark the thread, since the end of the catheter is the indication that a user will look for to determine the extent to pull the thread. Claims 14 and 15 are believed to present nonobvious subject matter over Weisman and Malecki.

Dependent claims 16-22 define further characteristics of the second end piece. Since neither Weisman nor Malecki describe or suggest a second end piece, the subject matter of claims 16-22 is believed to be not obvious over these references.

Dependent claims 23-25 define further characteristics of the first end piece. Weisman does not describe or suggest a first end piece, so the subject matter of these claims cannot be described or suggested by Weisman. While a curved end configuration on the forward end piece of a urinary catheter is common in those types of urinary catheters which are not fully inserted into the bladder, it is not common to have a through opening extending through the curved exterior end as is recited in these claims. Malecki is not relevant to urinary catheters. The subject matter of claims 23-25 is not believed to be obvious from Weisman and Malecki.

Dependent claims 26 and 27 also relate to a characteristic of the first end piece. Weisman does not describe the first end piece. Malecki's endovascular

cannula does not describe an end piece which has a greater transverse dimension than the body of his cannula. The significance of the improvements in claims 26 and 27 relates to insertion as described in the specification at page 8, line 12 to page 9, line 13. Such an arrangement is not described or suggested by Weisman or Malecki.

Claims 28-35 depend directly or indirectly on claim 13, and should be allowable in conjunction with claim 13, among other reasons.

Conclusion

For the reasons set forth, and others, it is believed that all pending claims in this application define patentable subject matter which is neither anticipated nor obvious from Weisman or Malecki. Accordingly, it is believed that the pending claims are in condition for allowance and such action is respectfully requested. The Examiner is requested to contact the undersigned by telephone to discuss any issues which may inhibit the immediate allowance of the claims.

Respectfully submitted,

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